

Registration of Department of Veterans Affairs Sponsored Clinical Trials FAQs

- **What is the definition of a “clinical trial”?**

The VA Office of Research & Development (ORD) currently uses a definition for clinical trials that is similar to that used by the International Committee of Medical Journal Editors (ICMJE).

This definition is “any research that prospectively assigns human subjects or groups of subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.”

If your study meets this definition, then it will have to be registered in order to be in compliance with ICMJE criteria.

The Cooperative Studies Program and Health Services Research & Development Service also require registration of retrospective and prospective observational studies that they fund.

- **When does a clinical trial need to be registered?**

Currently, ORD registers the clinical trials it sponsors upon notification of funding or shortly thereafter.

Any VA-sponsored clinical trial that will begin enrollment of participants on/after **July 1, 2005** must be registered before funding will be released. Additionally, this requirement will be consistent with ICMJE criteria for publication.

The ICMJE requires that ongoing clinical trials that are still enrolling participants after July 1, 2005 must be registered by **September 13, 2005**. For VA-sponsored clinical trials, ORD staff will work with investigators to ensure that there is compliance with this deadline.

- **How do I know if my clinical trial is registered?**

If you have a VA funded clinical trial, ORD staff may have already registered it at the National Library of Medicine’s clinicaltrials.gov registry. However, you should check to see if your trial is listed and has complete and accurate information. HSR&D investigators will be contacted by e-mail if their study is not registered.

If you have a clinical trial funded by another organization (e.g., NIH or industry), you will need to check with the sponsor to determine whether it is registered.

- **How does my clinical trial get registered?**

Currently, ORD staff has developed or is developing a system to identify the clinical trials it funds and has processes for uploading the necessary information to clinicaltrials.gov. Each research service has been proactively registering the clinical trials it sponsors and will continue to be responsible for ensuring that its respective trials are registered.

ORD staff will work with investigators to ensure that these clinical trials are registered at clinicaltrials.gov. However, investigators will need to provide ORD staff with required project information on the standardized Data Collection Form.